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MAY 21 2010

Sonic Shot GX Contrast Delivery System 510(k) Summary

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Proprietary Name:	Sonic Shot GX
Common Name:	Injector System
Classification Name:	Injector and Syringe, Angiographic
Predicate Device(s):	Optistar MR Injector System (K984088)
	Medrad Spectris Solaris MR Injector System (K042784)

Intended Use:

The contrast delivery system Sonic Shot GX is an intravascular injection system intended for the administration of MRI contrast media and normal saline solution used in conjunction with magnetic resonance imaging (MRI).

Description:

The contrast delivery system Sonic Shot GX is an intravascular injection system intended for the administration of MRI contrast media and saline used in conjunction with MRI.

The main components of the Sonic Shot GX are the Console, Powerhead and Main Control Unit. The Console resides in the control room or the MR suite, while the Main Unit and Powerhead reside in the scanning room alongside the MR scanning device and the patient. The parameters of the injection, such as volume, flow rate and pressure are programmed by the operator via the graphical user interface with touchscreen input. The Console is powered via 24 volts DC which is derived from a remote AC to DC converter (similar to that used with laptop computers) and communicates with Main Control Unit via a fiber-optic interface. The communication link is used to communicate the user set injection parameters to the Main Control and Powerhead located in the MR suite.

After the injection protocol has been set, the Powerhead performs the injection by driving one or two lead

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screw rams. The rams push the push-rod of the syringe which expels fluid from the barrel of the syringe. The following paragraphs provide more details for each of these main components.

POWERHEAD: The Powerhead provides a means for accepting and identifying a given syringe and then applying a force to the plunger of the syringe via its screw driven ram which will eject MR contrast or normal saline from the barrel of the syringe. The Powerhead is in constant communications with the Main Control Unit for determining injection protocol and to monitor all Powerhead functions and injection sequences. The injection information is communicated to the user Console to provide immediate feedback of injection operation. The Powerhead resides in the MR scanning room.

CONSOLE: The Console is the main user interface for the Sonic Shot GX. It provides a color graphical user interface with an overlying touchscreen for easy injection monitoring and injection setup. At the completion of an injection the injection result are clearly displayed to the user. The Console provides a connection for a remote Handswitch that can be used to start or stop an injection. The Console resides outside the MR scanning room and is typically located near the control console for the MR scanning equipment.

MAIN CONTROL UNIT: The Main Control Unit is the interface between the Console and the Powerhead. The Main Control Unit receives the user input data from the Console and converts to the necessary control information then relays to the Powerhead. The Main Control unit also provides the power necessary to operate the Powerhead. The Main Control Unit is located inside the MR scanning room and communicates with the Console via a fiber-optic cable.

The system is designed to deliver a variety of injection protocols. It can deliver single or multiple phase injections consisting of contrast, saline or both simultaneously. To enable the user to perform a variety of injection protocols the Powerhead provides for two syringes to be used and the Console provides a flexible user interface to enable simple and easy protocol setups. All protocols can then be stored onto a removable memory card. The injection system is also provided with a variety of consumables products for connecting the syringes to the patient.

SUBSTANTIAL EQUIVALENCE

A comparison chart shown in Table 1 compares the technological characteristics of the Sonic Shot GX contrast delivery system to the predicate devices the Liebel-Flarseim's Optistar MR and Medrad's Sprectris Solaris MR Injector System. The Sonic Shot GX is substantially equivalent to the predicate devices. The Sonic Shot GX injector system safely and effectively injects MR contrast and normal saline solutions as desired by the user in an MR environment.

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Characteristic / Feature	Optistar MR (Predicate device)	Sprectris Solaris (Predicate Device)	Sonic Shot GX (New Device)
Multi-phasic Contrast Injections	2 phases per protocol	2 phases per protocol	5 phases per protocol
Protocol Storage	20 protocols	20 protocols	
Injection History	Stores 20 injection results	Stores 5 injection results	Stores 20 injection results
Scan Delay	00:00 – 00:59 minutes	00:00 – 00:59 minutes	
Syringe System – A side	60ml or 25ml	65ml	60ml or 25ml
Syringe System – B side	60ml or 25ml	65ml	60ml or 25ml
Volume	1-61 in 1ml increments(60ml syringe) 1-27 in 1ml increments (25ml syringe)	1-63ml in 1ml increments	1-61 in 1ml increments(60ml syringe) 1-27 in 1ml increments (25ml syringe)
Flow Rate – A side	25ml syringe: 0.1 – 8.0ml/sec in 0.1ml/sec increments 60ml syringe: 0.1 – 10.0 ml/sec increments in 0.1 ml/sec increments	0.1 – 10.0 ml/sec increments in 0.1 ml/sec increments	25ml syringe: 0.1 – 8.0ml/sec in 0.1ml/sec increments 60ml syringe: 0.1 – 10.0 ml/sec increments in 0.1 ml/sec increments
Flow Rate – B side	25 and 60ml syringe: 0.1 – 7.0 ml/sec increments in 0.1 ml/sec increments	0.1 – 10.0ml/sec in 0.1ml/sec increments	25 and 60ml syringe: 0.1 – 7.0 ml/sec increments in 0.1 ml/sec increments
Pressure Limit	25ml syringe: 200psi 60ml syringe: 150psi	300psi	25ml syringe: 200psi 60ml syringe: 150psi
Remote Start Switch	Yes	Yes	Yes
Mode for keeping a vein open	Yes	Yes	Yes
Safety Stop Mechanism	Electrical stop when injection parameters are out of specification	Electrical stop when injection parameters are out of specification	Electrical stop when injection parameters are out of specification
User Interface Features			
- Fill / Expel Control	Push button on head	Push button on head	Push button on head
- Air Detection	Operator visual inspection	Operator visual inspection	Operator visual inspection
- Programming Injection	Touchscreen	Touchscreen	Touchscreen
- Status Display	Powerhead lights	Powerhead lights	Powerhead lights
Materials	Plastics and non-ferrous metals	Plastics and non-ferrous metals	Plastics and non-ferrous metals
Anatomical Sites	Venous injections	Venous injections	Venous injections
Intended Use Statement	The injection of MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans.	The injection of MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans.	The contrast delivery system Sonic Shot GX is an intravascular injection system intended for the administration of MRI contrast media and

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			normal saline solutions used in conjunction with magnetic resonance imaging (MRI).
Target Population	Humans	Humans	Humans
Sterility	Consumables are provided sterile	Consumables are provided sterile	Consumables are provided sterile
Body Weight Protocol programming method	No	No	Yes

SUMMARY OF PERFORMANCE TESTING

Performance testing was completed in order to verify the Sonic Shot GX contrast delivery system was capable of achieving the specification parameters for the system as outlined in the substantial equivalence chart. Verification of the system's ability to accurately achieve these values validates the substantial equivalence claims. Injection performance was tested to accuracy of delivered flow rate, volume (including Body Weight Protocol Programming Method), pressure, Drip Mode and manual control speeds.

VOLUME

Fluid delivery of an injector is characterized by three primary parameters, flow rate, volume and pressure limit. The volume delivered is the most critical parameter in that is has the greatest effect on image quality. During testing, the volume delivered was accurately measured and compared to the volume programmed. Over the range of volumes programmed, the Sonic Shot GX system successfully delivered the volumes within the allowable specifications.

FLOW RATE

The second most critical variable parameter in delivering fluid to a patient is the flow rate. During the test injections, the injection time and volume were recorded then the flow rate calculated. In the event of a pressure limit injection, the volume and time are known not to accurately represent the flow rate therefore the data was omitted from this specific calculation. In all non-pressure limited injections the flow rate measured within the allowable ranges of the specification. NOTE: Pressure limit injections automatically reduce the flow rate from the user set flow rate to maintain a constant pressure, as desired by the operator.

PRESSURE

During all injections, the injector monitors the pressure in order to determine if the injection should be pressure limited. An upper limit is set for each syringe type used in the injector in order to avoid failure of the syringe. During testing, the actual pressure was measured and compared to the displayed values and product specifications. All pressure readings were within the allowable specifications.

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BODY WEIGHT PROTOCOL PROGRAMMING METHOD

The volume of contrast required for an injection is based upon a patient's body weight. Normally, the amount of active ingredient (units: mmol/kg) are multiplied by the weight (kg) to give a volume (ml). The calculation is often performed manually or pre-calculated and a look-up sheet is provided to the clinician. The Sonic Shot GX provides a mode wherein this calculation can be performed by the injector as convenience for the operator. The Body Weight Protocol Programming does not predict the volume required, it simply calculates the volume based upon the patient weight and active ingredient units entered by the operator.

DRIP MODE

Drip Mode is used to keep a catheter or vein open. The injector achieves this by administering small increments of fluid (normal saline) over short time intervals. The injector allows the programming of the volume increment, time interval and flow rate. The performance of Drip Mode was evaluated during testing. Over the range of various Drip Mode parameters, the Drip Mode performance was within the allowable specification ranges.

MANUAL CONTROL SPEEDS

The Sonic Shot GX as two speeds for manually moving the rams. By depressing the forward or reverse keys on the Powerhead, the rams can be moved at 1ml/sec. By pressing the forward or reverse key in combination with the accelerator key, the rams can be moved at 5ml/sec. During testing, both speeds were confirmed on the A and B sides to be within the allowable specification range.

CONCLUSION

The Sonic Shot GX contrast delivery system provided its ability to perform within its specified parameters. As a result, its performance is deemed acceptable and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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MAY 21 2010

Re: K091734
Trade/Device Name: Sonic Shot GX
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II
Product Code: IZQ
Dated: February 15, 2010
Received: March 19, 2010

Dear Mr. Knipfer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k091734**

Device Name: Sonic Shot GX

Indications for Use:

The contrast delivery system Sonic Shot GX is an intravascular injection system intended for the administration of MRI contrast media and normal saline solution used in conjunction with magnetic resonance imaging (MRI).

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K091734